AUG 16 2005

Premarket Notification (510(k)) Summary

K052128

General Information

Sponsor

3M Company
3M Medical Division
3M Center
Building 275-5W-06
St. Paul, MN 55144-1000

Contact

Cynthia Lamarucciola
Phone: 651-736-1523
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Email: cllamarucciola@mmm.com

Prepared August 4, 2005

Device Name

Common or Usual Name: Auto-reader

Proprietary Name: 3M™ Attest™ 293 Auto-reader
3M™ Attest™ 293G Auto-reader

Classification Name: Biological Sterilization Process Indicators accessories (21CFR§880.2800).

Establishment Registration Number

The establishment registration number for 3M Company is 2110898.

The 3M™ Attest™ 293/293G Auto-readers are manufactured and packaged at the following facility:

3M Company
1617 North Front Street
New Ulm, MN 56073

Phone: 507-359-0434
Fax: 507-359-0334
Establishment Number 2183581

Device Classification

Class:	Class II
Classification Panel:	General Hospital (80)
Product Code:	FRC (accessory)

Indications for Use

The **3M™ Attest ™ 293** Auto-reader is designed to incubate and automatically read the 3M™ Attest ™ 1291 and/or 3M™ Attest ™ 1292 Rapid Readout Biological Indicators at 60° C for a final negative fluorescence reading at 1 hour for 1291 or 3 hours for 1292.

The 3M™ Attest ™ 293 Auto-reader is also designed to allow for further incubation of the Attest 1291 and/or the Attest 1292 Rapid Readout Biological Indicators for a final negative, visual pH color change of the growth media at 24 hours for 1291 and 48 hours for 1292.

The **3M™ Attest ™ 293G** Auto-reader is designed to incubate and automatically read the 3M™ Attest ™ 1294 Rapid Readout Biological Indicators (RRBI) for EO at 37°C for a final negative fluorescence reading at 4 hours.

Device Description

The 3M Attest 293 Auto-reader is an accessory to the 3M Attest series of Rapid Readout Biological Indicators (BI), which are incubated at 60 °C. The initial BIs in this series to receive market clearance were the 1291 (K900771) and 1292 (K926364).

The purpose of these BIs is to assess whether a potential failure of a steam sterilization cycle has occurred. Please note that both of these initial premarket notifications (K900771) and (K926364) listed the 3M Attest 190 Auto-reader as an accessory, subsequently the Model 290 Auto-reader was cleared (K004009) for use with these BIs and serves as the predicate device for the new Model 293 Auto-reader.

The Attest 293 is comprised of three (3) Attest 290 units within a single case.

The 3M Attest 293G Auto-reader is an accessory to the 3M Attest 1294 Rapid Readout EO Biological Indicator (RRBI) which is to be incubated at 37 °C.

The purpose of these BIs is to assess whether a potential failure of an ethylene oxide sterilization cycle has occurred. The model 290G was cleared (K031012) with the Attest 1294 BI and serves as the predicate for the 293G.

The Attest 293G is comprised of three (3) Attest 290G units within a single case.

Substantial Equivalence

The Attest 293 and 293G Auto-readers are substantially equivalent to the predicate Attest 290 and 290G Auto-readers in that they use the same fundamental technology, the same software, have the same indications for use and the same intended use. They are in fact a "three units within one case" configuration of the predicate.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 16 2005

Ms. Cynthia Lamanrucciola
Senior Regulatory Affairs Associate
3M Company
3M Center, Bldg. 275-5W-06
St. Paul Minnesota 55144-1000

Re: K052128
Trade/Device Name: 3M™ ATTEST™ 293 Auto-Reader
Regulation Number: 21 CFR 880.2800
Regulation Name: Biological sterilization process indicator
Regulatory Class: II
Product Code: FRC
Dated: August 4, 2005
Received: August 30, 2005

Dear Ms. Lamanrucciola:

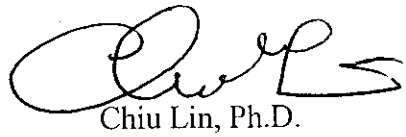
We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K052128

Device Name: 3M™ Attest™ 293 Auto-reader

Indications for Use:

The 3M™ Attest™ 293 Auto-reader is designed to incubate and automatically read the 3M™ Attest™ 1291 and/or 3M™ Attest™1292 Rapid Readout Biological Indicators for Steam, at 60°C for a final negative fluorescence reading at 1 hour for Attest 1291 or 3 hours for Attest 1292.

The 3M™ Attest™ 293 Auto-reader is also designed to allow for further incubation of the Attest 1291 and/or Attest 1292 Rapid Readout Biological Indicators for Steam, for a final negative, visual pH color change of the growth media at 24 hours for Attest 1291 and 48 hours for Attest 1292.

Device Name: 3M™ Attest™ 293G Auto-reader

Indications for Use:

The 3M™ Attest™ 293G Auto-reader is designed to incubate and automatically read the 3M™ Attest™ 1294 Rapid Readout Biological Indicators (RRBI) for EO, at 37°C for a final negative fluorescence reading at 4 hours.

Prescription Use ___ OR Over-the-Counter X

PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital,
Infection Control, Dental Devices

510(k) Number K052128